NOV 5 2002

SIEMENS

K022036

510(k) Summary

Submitter: Siemens Medical Solutions USA, Inc.
Oncology Care Systems Group
4040 Nelson Avenue
Concord, CA 94520

Contact person: Sean M. Curry
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Proprietary name: Siemens Virtual Simulation (VSIM)

Common name: Treatment Planning System

Classification: 892.5050

Product Code: MUJ

Classification name: System, Planning, Radiation Therapy Treatment

Substantial equivalence claimed to:
K013112, FocalSim, Computerized Medical Systems, Inc.
K923851 , ACQSIM, Philips Medical Systems(Cleveland), Inc.

Description:

Siemens Virtual Simulation (VSim) is a software application that runs on Siemens Medical Workstation, Syngo (K010938). It is intended to give the user general Viewing & Examination tools for viewing medical diagnostic images. Computed Tomography (CT) scans are the centerpiece of the diagnostic images used by the VSim. It will be possible to load other modality images, Positron Emission Tomography (PET) and Magnetic Resonance (MR), in conjunction with the CT images for treatment planning.

VSim is intended to provide tools for delineating and representing targets and critical Structures. It takes specifications and dimension information for the dose delivery system (Siemens and other vendors). It will then enable the user to design complex beam profiles and place them for optimum treatment of the disease. 3D Graphical representation and visualization of all the relevant objects allow for a virtual setup and treatment of the patient without involving the patient.

The VSim software will be used in a typical scenario summarized below:

- Patient is registered, and the relevant data is entered into the system,
- Schedule is created for radiation therapy,
- Patient is called in for a CT scan,
- CT scan is performed,
- VSim is used for initial viewing and definition of isocenter reference (for patient marking)
- Patient is marked prior to leaving the CT room,
- VSim is used to delineate the Structures targeted for radiation and other critical Structures,
- VSim is used to establish a reference point, known as the isocenter reference, which will be marked on the patient, and any other coordinates will be based on this reference coordinate,
- VSim is used to design the beam geometry,
- VSim is used to place the jaws and to define the blocks and/or MLC,
- VSim is used to print charts used for flow of information,
- VSim is used to print images on film,
- The plans are transferred to radiation therapy planning station for dose calculation,
- The isocenters may be changed by the dosimetrist,
- The plans may be transferred back to the VSim workstation for verification.

VSim is a 3D post-processing software application that uses CT planning images as input and creates the following data objects as output:

1. Structure sets stored in the form of DICOM-RT Structure-Set,
2. Reference Points (including isocenters) stored in the form of DICOM-RT Structure-Set,
3. Plans, including beams stored in the form of DICOM-RT-Plan, and
4. Reference Images in the form of Digitally Reconstructed Radiographs (DRRs), (one DRR for each beam in the plan) stored in the form of DICOM-RT-Image.

Intended use:

The SYNGO workstation, K010938, encompasses a number of software applications for viewing, processing, filming, and archiving of medical images. VSim is one of the software applications that are offered on the SYNGO workstation.

VSim permits CT Simulation to be performed on the SYNGO workstation. The CT scans are first loaded into the VSim software. On VSim the user is able to create 3D models of targets and organs. On VSim the user is able to identify the patient isocenter, place treatment beams and identify beam modifiers (blocks, apertures, and Multi-Leaf Collimators (MLCs)). This information is then sent to a radiation treatment planning system for dose calculation. The plans are then reviewed and approved by the clinician prior to transfer to the delivery system for the actual treatment.

Summary of technological characteristics Compared to Predicate Devices:
The VSim software described in this 510(k) will be an add-on to the SYNGO workstation, K010938. The VSim system incorporates no technological characteristics not currently in the predicate simulation devices. VSim supports the most popular CT Scanners as well as the three most common linear accelerators (Siemens, Varian, and Philips/Elekta)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Siemens Medical Solutions USA, Inc.
% Mr. Sean M. Curry
Chief Operating Officer
Certified Software Solutions, Inc.
16787 Bernardo Center Drive
Suite A
SAN DIEGO CA 92128

Re: K022036
Trade/Device Name: Siemens Virtual Simulation (VSIM) Release 1.0
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: 90 MUJ
Dated: October 18, 2002
Received: October 21, 2002

Dear Mr. Curry:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K022036

Device Name: Siemens Virtual Simulation (VSIM)

Indications for Use:

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lyerman

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K022036

Prescription Use V OR Over-the-Counter Use_____
(Per 21 CFR 801.109)